

## **REMARKS**

This Amendment is in response to the Office Action dated August 20, 2008. Each of the issues in the Office Action is addressed below. Currently claims 1-12, 14 and 16-29 are pending in the application with claims 8-9, 11-12 and 14 standing withdrawn.

### ***Claim Objections***

Claim 16 was objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

In response, claim 16 has been canceled due to its duplicity.

### ***§112 Rejections***

Claim 23 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

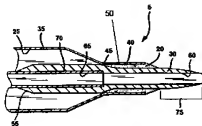
In response, claim 23 has been amended to further clarify the claimed subject matter.

### ***§102 Rejections***

Claims 1, 3-4, 18 and 29 were rejected under 35 U.S.C. §102(b) as being anticipated by Schwab et al. (US 5769819). A full account of the rejection is found on pages 3-4 of the Office Action.

Applicant respectfully disagrees with the rejection at least for the reason that the rejection fails to provide for the element that the distal tip layer extends distally to at least the distal end of the shaft and forms at least a portion of the distal end of the catheter, such that the distal tip layer is at least distally coextensive with the shaft, as required by independent claim 1.

In the rejection, figure 1 (shown below) of Schwab et al. is used to identify elements in claim 1 in an attempt to show anticipation. (In the figure shown below, reference numeral 50 has been added for illustrative purposes. The identification of the element is supported in figure 2.)

**FIG.1**

It is asserted in the rejection that the shown balloon distal tail 50 corresponds to the balloon distal waist in claim 1; that the adhesive fillet 20 corresponds to the distal tip layer in claim 1; and that the guide wire shaft 70 together with the distal tip extension 30 corresponds to the shaft in claim 1. The rejection fails at least for the reason that, even if the adhesive fillet 20 is considered to be a distal tip layer, as claimed in claim 1, it can not be said that “the distal end of the [adhesive fillet 20] extends distally to at least the distal end of the [guide wire shaft 70 together with the distal tip extension 30] and forms at least a portion of the distal end of the catheter, such that the [adhesive fillet 20] is at least distally coextensive with the [guide wire shaft 70 together with the distal tip extension 30]. As is clearly shown above in figure 1, the adhesive fillet 20 distally terminates well before the distal end of the guide wire shaft 70 together with the distal tip extension 30. As such, the rejection fails at least because it does not provide for each and every element of the claimed invention. Withdrawal of the rejection is therefore respectfully requested.

Claims 23-25 were rejected under 35 U.S.C. §102(b) as being anticipated by Lee et al. (US 6010521). A full account of the rejection is found on page 5 of the Office Action.

Although Applicant disagrees with the rejection, independent claim 23 has been amended to incorporate the subject matter of claim 26, which was not rejected under this rejection. Withdrawal of the rejection is therefore respectfully requested.

### ***§103 Rejections***

Claims 2 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over

Schwab et al. (US 5769819) in view of Wijay et al. (US 4921483). A full account of the rejection is found on pages 6-7 of the Office Action.

As mentioned above, claim 16 has been canceled due to its duplicative nature. As to claim 2, Applicant respectfully disagrees. It is asserted in the rejection that it would have been obvious to incorporate the increased length of the distal tip layer 72 (T) of Wijay et al. (shown below) to the system of Schwab et al. (reproduced again below) in order to add a soft distal end for decreased vascular trauma insertion. However, not only would it not be obvious, it would be directly

Wijay et al.

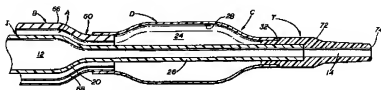
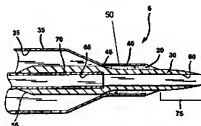


FIG. 3

Schwab et al.



**FIG.1**

contrary to the teachings of Schwab et al., it would not make sense in light of the designation of elements used in the §102 rejection addressed above based on Schwab et al.

In the above discussed §102 rejection based on Schwab et al., the adhesive fillet 20 is asserted to be the distal tip layer in claim 1 and the guide wire shaft 70 together with the distal tip extension 30 is asserted to be the shaft in claim 1. The present rejection asserts that Wijay et al. (see Fig. 3) would motivate one to extend the adhesive fillet 20 distally beyond the shaft 70

and distal tip extension 30 combination to form a protruding distal tip because the distal tip T of Wijay et al. extends beyond its inner shaft (inner body member I). However, it is clear that the catheter of Schwab et al. already has a "distal tip" (distal extension 30 shown above) that extends beyond its shaft 70. To one skilled in the art, it would be this distal extension 30 that corresponds to the distal tip T (called 72 in the rejection) of Wijay et al. and not the adhesive layer 20 that bonds the distal waist 50 of the balloon.

One skilled in the art would not consider it obvious to take teachings from one reference that instruct one to extend what it calls a distal tip distally beyond the catheter inner shaft and modify another catheter by ignoring that it already has an extended distal tip extension 30 and arbitrarily extending a totally separate and distinct element, that being the adhesive layer that secures the balloon waist to the catheter. To one skilled in the art, it would not have been obvious to modify the catheter of Schwab et al. in such a manner as asserted in the rejection in light of the teachings of the references. As such, the rejection fails at least for this reason withdrawal of the rejection is respectfully requested.

Claims 6-7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schwab et al. (US 5769819) in view of Larson et al. (US 6048338). It is asserted in the rejection that Schwab et al. meets the claim limitations as described in the §102 rejection on pages 3-4 of the office action except for a spiral cut layer. However, it is further asserted in the rejection that Larson et al. teaches a catheter with a spiral cut transition member with multiple layers. A full account of the rejection is found on pages 7-8 of the Office Action.

Applicant respectfully disagrees. Claims 6 and 7 depend indirectly from independent claim 1. The failure of the Schwab et al. rejection of claim 1 has been discussed above in response to the §102 rejection on pages 3-4 of the Office Action. Larson et al. do nothing to remedy the above-discussed deficiencies of the Schwab et al. rejection. Withdrawal of the rejection is therefore respectfully requested.

Claims 5, 10, 17 and 26-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schwab et al. (or Lee et al.). It is asserted that Schwab et al. or Lee et al. meets the claim limitations as described in previous rejections except for the specific disclosed materials

and tip length. A full account of the rejection is found on page 8 of the Office Action.

It is assumed by Applicant that, due to the fact that independent claim 1 was rejected based on Schwab et al. and claim 23 was rejected based on Lee et al., the rejection of claims 5, 10 and 17, which are indirectly and directly dependent upon claim 1, is based on Schwab et al. and the rejection of claims 26 and 27, which are indirectly and directly dependent upon claim 23, is based on Lee et al. As such, the claims are dealt with separately in the present response.

*Claim 5*

Claim 5 depends indirectly from independent claim 1. The failure of the Schwab et al. rejection of claim 1 has been discussed above in response to the §102 rejection on pages 3-4 of the Office Action. The present rejection does nothing to remedy the above-discussed deficiencies of the Schwab et al. rejection and as such similarly fails. Withdrawal of the rejection is therefore respectfully requested.

*Claim 10:*

Claim 10 depends directly on claim 2, which depends directly from independent claim 1. The failure of the Schwab et al. rejection of claim 1 has been discussed above in response to the §102 rejection on pages 3-4 of the Office Action and the failure of the Schwab et al. in view of Wijay et al. rejection of claim 2 has been discussed above in response to the §103 rejection on pages 6-7 of the Office Action. The present rejection does nothing to remedy the above-discussed deficiencies of the Schwab et al. and Wijay et al. rejection and as such similarly fails. Withdrawal of the rejection is therefore respectfully requested.

*Claim 17:*

Claim 17, as amended due to the cancellation of claim 16, depends directly from independent claim 1. The failure of the Schwab et al. rejection of claim 1 has been discussed above in response to the §102 rejection on pages 3-4 of the Office Action. The present rejection does nothing to remedy the above-discussed deficiencies of the Schwab et al. rejection and as such similarly fails. Withdrawal of the rejection is therefore respectfully requested.

*Claims 26-27:*

The subject matter of claim 26 has been incorporated into independent claim 23 and claim 27 has been canceled due to redundancy. As such, the present rejection is being treated as applying to newly amended claim 23.

With regard to newly amended claim 23, the rejection asserts that Lee et al. meets the claim limitations as described in previous rejections except for the specific disclosed materials. It is further asserted in the rejection that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Lee et al. with the materials as claimed by Applicant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. The rejection cites *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Applicant respectfully disagrees. *In re Leshin* states that “[m]ere selection of known plastics to make a container-dispenser of a type made of plastics prior to the invention, the selection of the plastics being on the basis of suitability for the intended use, would be entirely obvious.” *In re Leshin*, 125 USPQ 416, 417-418 (CCPA 1960) However, this is not the case in the present claim to particular materials. In *In re Leshin*, the item was a container-dispenser which was made of a material, that being plastic. The use of plastic for such type of containers was known and it was shown to be known and admitted to be known.

Claim 23 now requires that “the first tubular layer comprises a layer of EA20HV1 Grilamid; EA-Nylon 12 (modified) 20-medium viscosity HVI-Adhesion (modified) and a layer of thermoplastic polyester elastomer or polyether-ester copolymer”. This is not just a claim that the first tubular layer is made from a material which is shown to be known to be used for layers of this type. The first tubular layer comprises *two* layers wherein each of the two layers comprises a *different* material. The rejection fails to provide for the two distinct layers and further fails to provide for the requirement that the two distinct layers are of two distinct materials. The rejection further fails to show that any of the claimed materials were known or admitted to be known to be used for tubular layers of this type. As such, withdrawal of the rejection is respectfully requested.

Claims 19-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over

Schwab et al. (US 5769819) in view of Lee et al. (US 6010521). It is asserted in the rejection that Schwab et al. meet the claim limitations as described in the §102 rejection based on Schwab et al. except for the thermally bonded intermediate layer. A full account of the rejection is found on pages 9-10 of the Office Action.

Claims 19-22 depend directly and indirectly from independent claim 1. The failure of the Schwab et al. rejection of claim 1 has been discussed above in response to the §102 rejection on pages 3-4 of the Office Action. The present rejection does nothing to remedy the above-discussed deficiencies of the Schwab et al. rejection and as such similarly fails. Withdrawal of the rejection is therefore respectfully requested.

***Suggested Subject Matter***

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration. Examiner suggested the addition and further clarification of the spatial location/structure and length of the spiral cut layer to the independent claims.

In response, claim 7 has been amended to further clarify the spiral cut. Favorable consideration is respectfully requested.

**Conclusion**

Based on at least the above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-7, 10, 17-25 and 29 and reinstatement of withdrawn claims 8-9, 11-12, 14 and 28 is requested. Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,

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